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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,784	10/12/2001	Maximilian Polyak	053137-5001	2223

7590

06/16/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/976,784

Applicant(s)  
Polyak et al.

Examiner  
Sandra Saucier

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 28, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) 6-8, 13-18, and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,5 6) ☐ Other:

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#### **DETAILED ACTION**

Claims 1-27 are pending. Claims 1-5, 9-12 and 19 are considered on the merits. Claims 6-8, 13-18, 20-27 are withdrawn from consideration as being drawn to a non-elected invention.

#### ***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the grounds that a reasonable number of species should be examined provided that the application also includes an allowable claim generic to the claimed species. This is not found persuasive because the generic claim is not allowable.

Applicant further argues that no showing of undue burden has been made. Please see page 4, paragraph 1 of the restriction requirement for a discussion of undue burden.

Claims to a method of use of the composition may be rejoined upon the finding of an allowable composition.

#### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 06-305901 [IDS].

The claims are directed to a composition comprising:

- a) a cellular energy production stimulator (insulin),
- b) an anti-inflammatory agent (dexamethasone),
- c) an oxygen free-radical scavenger (SOD).

The references are relied upon as explained below.

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JP 06-305901 discloses a composition comprising insulin, dexamethasone and PEGylated SOD.

Claims 1-4, 9-12 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Caldwell-Kenkel *et al.* [U] in light of US 4,879,283 [IDS].

The claims are directed to a composition comprising:

- a) insulin 4-100U/L,
- b) dexamethasone 4-24 mg/L
- c) SOD 1000-100,000U/L,
- d) potassium lactobionate 50-150mM,
- e)  $\text{KH}_2\text{PO}_4$  10-40mM,
- f) magnesium sulfate 2-8mM,
- g) raffinose 10-50mM,
- h) adenosine 1-20mM,
- i) allopurinol 1-10mM,
- j) pentastarch 40-60g/L.

Caldwell-Kenkel *et al.* disclose UW solution supplemented with c) SOD 25 U/ml (Table 6). UW solution is old in the art and is disclosed in US 4,879,283 as comprising:

- a) insulin 100 U/L,
- b) dexamethasone 8 mg/L
- d) potassium lactobionate 100mM,
- e)  $\text{KH}_2\text{PO}_4$  25mM,
- f) magnesium sulfate 5mM,
- g) raffinose 30mM,
- h) adenosine 5mM,
- i) allopurinol 1mM,
- j) pentastarch 50g/L.

Use of the terms "about" in the claimed solution, without definition of the range of "about" permits interpretations that place the concentrations claimed to be "about" the disclosed concentrations.

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***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–4, 9–12 and 19 are rejected under 35 U.S.C. 103 as being obvious over Caldwell–Kenkel *et al.* [U] in combination with US 4,798,824 [IDS] or SU 1074471 [N].

The claims are further directed to the use of about 40 U/L insulin.

Caldwell–Kenkel *et al.* has been discussed above.

SU 1074471 discloses the inclusion of 35–45U/l insulin in a solution for kidney preservation.

US 4,798,824 discloses the use of 40U/ml insulin in a solution for kidney preservation (Table 1).

The use of insulin in a range of 35–100U/L in the composition of Caldwell–Kenkel *et al.*, would have been obvious because insulin has been used in the prior art in concentrations of 35–100U/L.

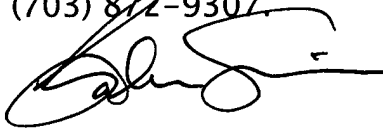
One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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All components of the claimed composition near the concentrations of the claims have been used in the prior art for the same purpose as the instant purpose. No claim is allowed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
June 13, 2003